

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 19 APR 2006


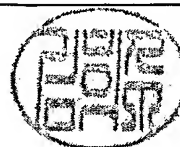
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Applicant's or agent's file reference OP03-0162	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. <b>PCT/KR2003/002637</b>	International filing date(day/month/year) <b>03 DECEMBER 2003 (03.12.2003)</b>	Priority date (day/month/year) 26 NOVEMBER 2003 (26.11.2003)	
International Patent Classification (IPC) or national classification and IPC  <b>A61K 9/48(2006.01)i</b>			
Applicant  <b>PARK Hyun-Jin et al</b>			

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
  - ☒ (sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:
    - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand  <b>24 JUNE 2005 (24.06.2005)</b>	Date of completion of this report  03 MARCH 2006 (03.03.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  KIM, Hee Sue  Telephone No. 82-42-481-5605 

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2003/002637

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☒ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
  
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
  - ☐ the international application as originally filed/furnished
  - ☒ the description:
 

pages <u>1-15, 17-22, 24-25</u>	as originally filed/furnished
pages* <u>16, 23</u>	received by this Authority on <u>17.01.2006</u>
pages* _____	received by this Authority on _____
  - ☒ the claims:
 

pages <u>28</u>	as originally filed/furnished
pages* _____	as amended (together with any statement) under Article 19
pages* <u>26-27</u>	received by this Authority on <u>17.01.2006</u>
pages* _____	received by this Authority on _____
  - ☐ the drawings:
 

pages _____	as originally filed/furnished
pages* _____	received by this Authority on _____
pages* _____	received by this Authority on _____
  - ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
  
3. ☒ The amendments have resulted in the cancellation of:
  - ☐ the description, pages \_\_\_\_\_
  - ☒ the claims, Nos. 2
  - ☐ the drawings, sheets \_\_\_\_\_
  - ☐ the sequence listing (*specify*): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
  
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, Nos. \_\_\_\_\_
  - ☐ the drawings, sheets \_\_\_\_\_
  - ☐ the sequence listing (*specify*): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2003/002637

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims	1-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

The description on pages 16, 23 and claims 1, 6 have been amended, and claim 2 has been deleted. These scopes have not been extended beyond the disclosure of the patent application as filed.

The present invention relates to a film-forming composition suitable for hard capsules, and a preparation method thereof, and more particularly to a film-forming composition comprising the starch which contains 10-30% by weight of amylose such as potato starch, waterchestnut starch or mungbean starch and a preparation method thereof.

The following document has been considered for the purpose of this report:

D1 = WO 00/18835 (06 April 2000)

#### 1. Novelty

D1 discloses compositions from modified starches, such as starch ethers or oxidized starch, more particularly hydroxypropylated starch(HPS) or hydroxyethylated starch(HES) for the use in pharmaceutical, veterinary, food, cosmetic or other products like films for wrapping food, aspics or jellies, preferably for predosed formulations like soft or hard capsules.

A film-forming composition comprising the starch which contains 10-30% by weight of amylose such as potato starch, waterchestnut starch or mungbean starch and a preparation method thereof are not disclosed in any of the prior art. The subject matter of claims 1-12 can therefore be considered novel under PCT Article 33(2).

(Continued on Supplemental Sheet.)

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.  
Continuation of:

Box. V

**2. Inventive Step**

Even though D1 is relevant to the present invention, there is no indication in cited document which would have led the skilled person to use the starch comprising 10-30% by weight of amylose such as potato starch, waterchestnut starch or mungbean starch to prepare a film-forming composition suitable for hard capsules. Also, the applicant shows the advantages such as excellent water-soluble, biodegradable and edible properties, compared with the comparative example.

Therefore, the subject matter of claims 1-12 is considered to involve an inventive step under PCT Article 33(3).

**3. Industrial Applicability**

The subject matter of claims 1-12 is considered to be industrially applicable under PCT Article 33(4).

Experimental Example 3: Determination of gelling agent amount suitable for hard capsules

In order to determine the amount of the gelling agent suitable for the preparation of hard capsules, the present inventors have prepared the hard capsules and films comprising the gelling agent in various amounts as shown in Table 3 below, in the same manner as in Experimental Example 1. Potato starch was used as the starch, glycerol as the plasticizer, and  $\kappa$ -carrageenan as the gelling agent. The amounts of the starch and the plasticizer were set to about 9% by weight and about 2-3% by weight, respectively, which are in the optimum amount ranges determined in Experimental Examples 1.

[Table 3]

Determination of amount of gelling agent suitable for hard capsules

	Amount of addition (g)								
Potato starch	45	45	45	45	45	45	45	45	45
Glycerin	11.25	11.5	11.75	12	12.25	12.5	12.75	13	13.25
$\kappa$ -carrageenan	0	1	2	3	4	5	6	7	8
Water	450	450	450	450	450	450	450	450	450
Total amount	506.25	507.5	508.75	510	511.25	512.5	513.75	515	516.25
Mungbean starch	45	45	45	45	45	45	45	45	45
Glycerin	13.5	13.75	14	14.25	14.5	14.75	15	16.25	17.5
$\kappa$ -carrageenan	9	10	11	12	13	14	15	20	25
Water	450	450	450	450	450	450	450	450	450
Total amount	517.25	518.75	520	520.25	522.5	523.75	525	531.25	537.5

solution was too viscous, so that tailing upon the preparation of capsules occurred, or bubbles were not removed, or the thickness of the film was not uniform.

#### (6-2) Preparation of waterchestnut starch-hard capsules

Hard capsules and films were prepared with compositions described in Table 11 below in the same manner as in Experimental Example 1 except that the step of adding the gelling agent was not performed.

[Table 11]

Preparation of waterchestnut starch-hard capsules with no addition of gelling agent

	Amount of addition (g)												
waterchest nut starch	5	10	15	20	25	30	35	40	45	50	55	60	65
Glycerin	1.25	2.5	3.75	5	6.25	7.5	8.75	10	11.25	12.5	13.75	15	16.25
Water	450	450	450	450	450	450	450	450	450	450	450	450	450
Total amount	456.2 5	462.5	468.7 5	475	481.2 5	487.5	493.7 5	500	506.2 5	512.5	518.7 5	525	531.2 5

As shown in FIG. 7, the results showed that, if the amount of the waterchestnut starch was 25-55 g, it would be prepared into hard capsules even when the gelling agent was not added, similarly to the case of the mungbean starch.

#### Example 7: Examination of characteristics of starch

**What is claimed is:**

1. (Amended) A film-forming composition for hard capsules, comprising 7-12% by weight of starch, 1-6% by weight of a plasticizer, 0.7-3% by weight of a gelling agent, and 79-91.3% by weight of water, wherein the starch comprises 10-30% by weight of amylose.

2. (Deleted)

3. The composition of Claim 1, wherein the starch is selected any one from the group consisting of potato starch, waterchestnut starch, and mungbean starch.

4. The composition of Claim 1, wherein the plasticizer is any one selected from the group consisting of glycerol, sorbitol, polyethylene glycerol (PEG), mannitol, maltitol, and mixtures thereof.

5. The composition of Claim 1, wherein the gelling agent is any one selected from the group consisting of carrageenan, agar gum, pectin, alginate, gum arabic, xanthan gum, gellan, and mixtures thereof.

6. (Amended) A method for preparing a film-forming composition for hard capsules, the method comprising the steps of:

(a) adding 1-6% by weight of a plasticizer based on the total weight of the composition to 79-91.3% of water based on the total weight of the composition, and stirring the solution at 25-60 °C;

(b) adding 0.7-3% by weight of a gelling agent based on the total weight of the composition to the solution prepared in the step (a), and stirring the gelling agent-comprising solution at  $50 \pm 5$  °C; and

(c) adding 7-12% by weight of starch based on the total weight of the composition to the solution prepared in the step (b), wherein the starch comprises 10-30% by weight of amylose, and stirring the starch-comprising solution while gradually elevating the temperature of the solution to  $90 \pm 5$  °C.

7. A film-forming composition for hard capsules, comprising 5-11% by weight of waterchestnut starch or mungbean starch, 1-3% by weight of a plasticizer, and 88-94% by weight of water.

8. The composition of Claim 7, wherein the starch comprises 24-30% by weight of amylose.

9. The composition of Claim 7, wherein the plasticizer is any one selected from the group consisting of glycerol, sorbitol, polyethylene glycerol (PEG), mannitol, maltitol, and mixtures thereof.

10. A method for preparing a film-forming composition for hard capsules, the method comprising the steps of:

(a) adding 1-3% by weight of a plasticizer based on the total weight of the composition to 88-94% by weight of water based on the total weight of the composition, and stirring the solution at 25-60 °C; and

(b) adding 5-11% by weight of waterchestnut starch or mungbean starch based on the total weight of the composition to the solution prepared in the step (a),